K082810

4 510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Nancy Hoft Regulatory Affairs Associate Arthrex, Inc 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone 239/643 5553, ext. 1113 Fax 239/598 5508 Email nancy hoft@arthrex.com JAN 23 2009
Trade Name	**Arthrex Bio-Composite Suture Anchors** Arthrex Bio-Composite PushLock, Bio-Composite Tak and Bio-Composite Corkscrew
Common Name	Suture Anchor
Product Code - Classification Name	**HWC** -Screw, Fixation, Bone **MBI** - Fastener, Fixation, Nondegradable Soft Tissue **JDR** - Staple, fixation, bone **MAI** - Fastener, Fixation, Biodegradable, Soft Tissue
Predicate Device	Arthrex Bio-Composite Suture Anchors K071177
Device Description and Intended Use	The **Arthrex Bio-Composite Suture Anchors Family** is identical to the predicate devices The **Arthrex Bio-Composite Suture Anchor Family** is intended to be used for • Fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, elbow, and pelvis • For suture or tissue fixation in the foot, ankle, hip, hand, wrist, elbow, shoulder, and in select maxillofacial applications where size is appropriate See the Indications for Use statements for specific indications
Substantial Equivalence Summary	The **Arthrex Bio-Composite Suture Anchor Family** is substantially equivalent to the predicate **Arthrex Bio-Composite Suture Anchor Family** in which the basic features and intended uses are the same Any differences between the *Bio-Composite Suture Anchor Family* and the predicate K071177 are considered minor and do not raise questions concerning safety and effectiveness Based on the information submitted, Arthrex, Inc has determined that the new *Bio-Composite Suture Anchor Family* is substantially equivalent to the currently marketed predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrex Inc
% Ms Nancy Hoft
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

JAN 2 3 2009

Re K082810
Trade/Device Name Bio-Composite Suture Anchors, Expansion of Indications to include Hip
Regulation Number 21 CFR 888 3040
Regulation Name Smooth or threaded metallic bone fixation fastener
Regulatory Class II
Product Code MAI, HWC
Dated January 20, 2009
Received January 21, 2009

Dear Ms Hoft

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K082810

Device Name. **Arthrex Bio-Composite PushLock™**

The **Arthrex Bio-Composite PushLock™** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, hip, and pelvis in the following procedures

Shoulder:	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
Foot/Ankle	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.
Elbow.	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair
Pelvis	Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency
Hip	Capsular Repair, acetabular labral repair

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082810

3 Indications for Use Form

Indications for Use

510(k) Number K082810

Device Name: **Arthrex Bio-Composite Corkscrew®**

The **Arthrex Bio-Composite Corkscrew** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

Hip: Capsular Repair, acetabular labral repair

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for Use

510(k) Number K082810

Device Name: **Arthrex Bio-Composite Tak**

The **Arthrex Bio-Composite Tak™** is intended to be used for suture or tissue fixation in the foot, ankle, knee, hip, hand, wrist, shoulder, elbow, and in select maxillofacial applications Specific indications are listed below and are size appropriate per patient needs

Skull: Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, Soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and periorbital bones of the skull.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Hand/Wrist. Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, Digital Tendon Transfers

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot reconstruction.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

Hip: Capsular Repair, acetabular labral repair

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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